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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/622,745	08/22/2000	Anders Edlund	1103326-0633	2661

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White & Case
1155 Avenue of the Americas
New York, NY 10036-2787

EXAMINER

LANDSMAN, ROBERT S

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 01/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/622,745

Applicant(s)

EDLUND ET AL.

Examiner

Robert Landsman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 32-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. Formal Matters

- A. The response, filed 9/30/03, has been entered into the record. Applicants stated that there appeared to be some confusion regarding the status of the claims. Therefore, in summary, claims 1-31 are canceled. Therefore, claims 32-47 are pending and are the subject of this office action.
- B. All Statutes not found in this Office Action can be found, cited in full, in a previous Office Action.

2. Claim Objections

- A. The objection to claims 32-47 has been withdrawn in view of Applicants' amendment to the claims to remove the term "hosting."
- B. Claims 32-47 remain rejected for the reasons already of record on page 2 of the Office Action dated 5/20/03 regarding the term "constituting." Applicants did not address this part of the objection. It is suggested that the term "comprising" be used.
- C. The objection to claims 35, 36, 40 and 41 regarding failing to further limit the parent claim, has been withdrawn in view of Applicants' amendments to the claims to recite that the transcription factors have been transfected into the cell.

3. Specification

- A. The specification is objected to since According to 37 CFR 1.821(d) (MPEP § 2422), where the description or claims of a patent application discuss a sequence listing that is set forth in the "Sequence Listing" in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the assigned identifier, in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application. Sequences appear on page 15 (Table I), of the specification but are not identified by SEQ ID NO as required.

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4. Claim Rejections - 35 USC § 112, first paragraph – scope of enablement

A. Claims 37-47 remain rejected under 35 USC 112, first paragraph, for the reasons already of record on pages 3-4 of the Office Action dated 5/20/03. Applicants argue that the Examiner has indicated in the outstanding Office Action (see, e.g., page 4, lines 16-18) that replacement of the word “form” with the word “variant” would be remedial and it cannot be said that new matter is introduced by this amendment. This arguments has been considered, but is not deemed persuasive. The Examiner apologizes for suggesting the use of the word “form” in place of the word “variant.” However, this does not remedy the situation. Though the claims also recite the limitation that the promoter has to be “at least 95% identical” to SEQ ID NO:1 or 2, the specification still does not enable the artisan to make these “variants.” It is suggested that the phrase “functionally equivalent modified variant” be removed from the claims. This would not only remedy the situation, but would also broaden the scope of the claims.

B. Claims 32-47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As discussed with Richard Sterner, the claims recite a method of screening compounds for modulation of GABA receptor transcription by providing a host cell which has been transfected with a promoter of SEQ ID NO:1 or 2, or a variant thereof, a reporter gene, and measuring whether a test compound modulates the effect of a reporter gene. However, there is no discussion in the specification, including guidance or working examples, that the promoter actually modulates GABA receptor expression, nor do the claims remedy this deficiency. Nothing in the claims allows the artisan, practicing this invention, to determine that a compound in which the only requirement is to modulate reporter gene expression, actually affects GABA receptor transcription.

5. Claim Rejections - 35 USC § 112, first paragraph – written description

A. Claims 37-47 remain rejected under 35 USC 112, first paragraph, for the reasons already of record on pages 5-6 of the Office Action dated 5/20/03. Applicants arguments are identical to those seen above regarding 35 USC 112, first paragraph – enablement. Therefore, these arguments are not deemed persuasive for the reasons discussed in the above paragraph under 35 USC 112, first paragraph, enablement. Namely, though the claims also recite the limitation that the promoter has to be “at least 95% identical” to SEQ ID NO:1 or 2, the specification still does not adequately describe these “variant.” It is

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suggested that the phrase “functionally equivalent modified variant” be removed from the claims. This would not only remedy the situation, but would also broaden the scope of the claims.

6. Claim Rejections - 35 USC § 112, second paragraph

A. The rejection of claims 32-47 under 35 USC 112, second paragraph, has been withdrawn since it is clear that the “active fragments,” “functionally equivalent modified variants” and sequences which are “at least 95% identical” to SEQ ID NO:1 and 2 have promoter activity.

B. Claims 32-47 remain rejected under 35 USC 112, second paragraph, for the reasons already of record on pages 6-7 of the Office Action dated 5/20/03. The claims recite a method of screening compounds for modulation of GABA receptor transcription by providing a host cell which has been transfected with a promoter of SEQ ID NO:1 or 2, or a variant thereof, a reporter gene, and measuring whether a test compound modulates the effect of a reporter gene. However, there is no discussion in the specification, including guidance or working examples, that the promoter actually modulates GABA receptor expression, nor do the claims remedy this deficiency. Nothing in the claims allows the artisan, practicing this invention, to determine that a compound in which the only requirement is to modulate reporter gene expression, actually affects GABA receptor transcription.

C. Claims 35 and 40 are rejected under 35 USC 112, second paragraph, since they are confusing due to the recitation of “specific.” Applicants addition of the phrase “has been further transfected with” to these claims to comply with the rejection of paragraph 6C of the Office Action dated 5/20/03 makes this claim clear. It is suggested that the term “specific” be removed.

D. The rejection of claim 37 under 35 USC 112, second paragraph, regarding whether or not both parts (1) and (2) comprise parts (i) and (ii), though the claim would be clearer if it was amended to recite “wherein said promoter element is selected from the group.”

E. Claims 32-47 remain rejected under 35 USC 112, second paragraph, for the reasons already of record on page 6 of the Office Action dated 5/20/03. Applicants argue that the transitional phrase ‘consisting essentially of’ limits the scope of a claim to the specified materials or steps ‘and those that do not materially affect the basic and novel characteristic’ of the claimed invention (In re Herz). Thus, the

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“metes and bounds” of the essential elements of the invention are clear when this transitional phrase is used. This can be contrasted to what MPEP 2111.03 says about the transitional term “comprising.” Said term is inclusive or open-ended and does not exclude additional, unrecited elements or method steps.”

This argument has been considered, but is not deemed persuasive. The use of the phrase ‘consisting essentially of’ was used in the context of compounds, where impurities could be present. This is not the situation here.

F. The rejection of claims 37-47 under 35 USC 112, second paragraph, regarding “functionally equivalent modified form” has been withdrawn in view of Applicant’s amendment to the claim to replace the term “derivative” with “variant.”

G. The rejection of claims 37-47 under 35 USC 112, second paragraph, regarding “active fragment” has been withdrawn in view of the fact that numerous active fragments have been described in the specification and Figures.

H. Claims 42 and 44 are confusing since it is not clear if the “functionally equivalent modified variant” has to be at least 95% identical to either SEQ ID NO:1 or 2, respectively, or if the methods are using a functionally equivalent modified form of any promoter at least 95% identical to SEQ ID NO: 1 or 2, respectively - implying that the modified form could have any number of changes to SEQ ID NO:1 and 2. Claims 43 and 45-47 are rejected since they depend from claims 42 or 44.

I. The rejection of claims 43 and 46 regarding the term “not operably linked” has been withdrawn in view of the fact that, upon further consideration, the Examiner has concluded that this phrase is clear.

7. Conclusion

A. No claim is allowable.

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Advisory information

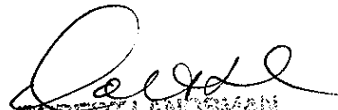
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
January 12, 2004


ROBERT LANDSMAN
PATENT EXAMINER